MINAKEM® HIGH POTENT

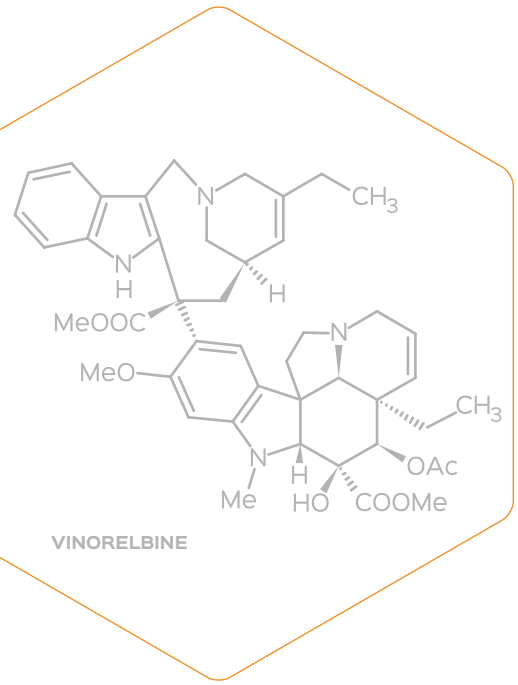
HIGHLY ACTIVE & CONTROLLED SUBSTANCES

MINAKEM HIGH POTENT S.A.
was established in June 2015 following the acquisition by Minafin Group of the former Ajinomoto OmniChem Louvain-la-Neuve dedicated HAPI site. Our state-of-the-art high containment facility delivers high quality products and services throughout the full product life cycle since 1972. With a local team of more than 100 employees the site has become a trusted development partner and commercial manufacturer for global pharmaceutical companies.

MINAFIN® GROUP

DEVELOPMENT AND MANUFACTURING OF HIGHLY ACTIVE PHARMACEUTICAL INGREDIENTS (HAPI)

- High containment systems down to OEB Class 5 (1 - 0.1 µg/m³ · shift) for manufacturing facilities, process research and analytical laboratories
- Multipurpose plant with 40+ years of experience in HAPI manufacturing
- Capacity from grams to hundreds of kilos of HAPI to support clients from early clinical to commercial phases
- Process development and scale-up
- Excellent inspection track record (US-FDA inspected site since 1983, latest inspection September 2015 without 483)
- Regulatory affairs department for compilation and submission of registration files (CMCs, DMFs, CEPs)
- Equipped and staffed to handle demanding custom manufacturing HAPI projects
- Generic HAPI portfolio for oncology and pain treatment (Vinca alkaloids and opiates)
- Authorized by Belgian authorities to handle controlled substances ("narcotics") on production scale



VINORELBINE

CATALOG PRODUCTS

PRODUCT	REGULATORY DOCUMENTATION
VINORELBINE tartrate	CEP, US-DMF
VINBLASTINE sulfate	CEP, US-DMF
VINCRISTINE sulfate	CEP, US-DMF
VINDESINE sulfate	ASMF
HYDROMORPHONE HCl	ASMF
MORPHINE derivatives	
CODEINE derivatives	

HIGH CONTAINMENT

The trend in pharmaceutical industry is to develop increasingly potent active pharmaceutical ingredients (HAPIs) to address a number of unmet medical needs. The Minakem High Potent site offers state-of-the-art high containment development, analytical and manufacturing facilities staffed with exceedingly well trained personnel to handle HAPIs with occupational exposure limits (OEL) down to 0.1 µg/m³ · shift (OEB class 5) safely from early clinical phase development through scale-up and commercial manufacturing.

Minakem High Potent is located at the Fleming Science Park in the vicinity of the well-known University of Louvain-la-Neuve. Through our excellent contacts with their science departments we ensure access to highly qualified academics trained in latest technologies of organic synthesis.

YOUR PARTNER FOR ONCOLOGICS AND NARCOTICS MANUFACTURING

MANUFACTURING ASSETS AND TECHNOLOGIES

- Four multi-purpose high-containment manufacturing trains with equipment ranging from 50 L to 1600 L (GL, SS, Hastelloy)
- Glove box isolators equipped with alpha beta rapid transfer ports to enable charging, filtration, drying, milling, discharging, weighing and packaging unit operations in full containment
- Capability to handle highly potent compounds down to 0.1 µg/m³ · shift (OEB class 5)
- Small-scale glass vessels from 2 L to 20 L
- HAPI batch sizes from 100 g to 100 kg
- Freeze-drying of up to 1.1 kg of bulk HAPIs
- Purification and synthetic modification of natural product extracts derived from Vinca Rosea and Papaver Somniferum
- Liquid-liquid extraction and HPLC on preparative scale
- Low temperature reactions down to –80°C
- Hydrogenation, oxidation and handling of hazardous compounds (anhydrous hydrazine, acetone cyano hydrine, LiHMDS, NaHMDS, etc.)

R&D AND PROJECT MANAGEMENT

Our process research and development team complemented by analytical development specialists and dedicated project managers consists of more than 17 industry professionals focusing on

- route scouting
- process development, optimization and scale-up
- Quality by Design (QBD) as stipulated by the ICH Q11 guidelines to perform impurity mapping and evaluate Normal Operating Ranges (NOR) and Proven Acceptable Ranges (PAR)
- development, optimization and validation of analytical methods
- process transfer to our full scale manufacturing units
- ongoing continuous process improvement throughout the lifecycle of the product
- HAPI stability studies according to ICH Q1A guidelines

To ensure optimal bi-directional information flow, communication with the client is handled by dedicated project managers as single points of contact (SPOC) for all technical aspects of a project.
As part of our ongoing continuous improvement process we identify alternative manufacturing routes with the goal of improving product quality and reducing product cost as well as waste and environmental impact.
All our teams are located on the same site allowing for an efficient transfer of information on process and analytical details. Maintaining a close cooperation with affiliated sites within the Minafin group allows us to rapidly outsource large volume, non high-potent early steps.

COMPLIANCE

As a preferred HAPI supplier of global pharmaceutical companies we have a track record of successful inspections with regulatory authorities (US-FDA, PMDA, ANSM, INCB, Korean FDA) as well as the local safety, health and environmental (SHE) agencies. "Safety First" is at the heart of our SHE policies which provide our guideline for rigorous and continuous safety training.
To minimize product cross-contamination we have implemented product-specific cleaning and change-over procedures taking into account Maximum Allowable Carryover (MACO) values as defined by the APIC guidelines on cleaning validation in API plants.
With our expertise in regulatory affairs we compile and submit CMC parts, DMFs and CEPs, thus enabling our clients to file with regulatory authorities in a seamless and efficient manner.
Through thorough training we have implemented a continuous improvement culture using operational excellence lean six sigma tools such as 5S Kaizen and structured root cause analyses (RCAs).

MINAKEM® HIGH POTENT
HIGHLY ACTIVE & CONTROLLED SUBSTANCES

MINAKEM HIGH POTENT S.A.
Rue Fonds Jean Pâques, 8
B-1435 Mont-Saint-Guibert
Belgium
T +32 10 238 456
contact-MHP@minakem.com
www.minakem-high-potent.com

MINAFIN® GROUP